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SUBJECT: GOI WELCOMES DIALOGUE WITH PHARMA INDUSTRY

REF: SECSTATE 162295

(SBU) 1. SUMMARY: Ministry of Economic Development Director General for Innovation and Competition Andrea Bianchi received our demarche on pharmaceutical reimbursements, noted USG concerns about the GOI's pharmaceutical reimbursement scheme, and vowed to find a solution to remove the potential for patent infringements. Bianchi expressed a ready willingness to meet with pharmaceutical industry representatives to discuss pricing and related issues further. In our discussion, he identified the pharmaceutical industry as a key sector for the Italian economy as it pursues domestic and foreign investment; innovation and R&D. To that end, Bianchi outlined new GOI tax incentives to encourage R&D. END SUMMARY.

(SBU) 2. EmbOffs met Ministry for Economic Development Director General for Competition Bianchi on December 11. He was sensitive to USG concerns about the threat the GOI's pharmaceutical reimbursement scheme poses to innovation (reftel), but explained that the plan aims to foster innovation by encouraging new drug entries to market rather than sustaining drugs nearing the end of their patent life. He also claimed that the payback scheme is more transparent than previous efforts to stabilize drug prices. According to Bianchi, since the reimbursement scheme does not call for suddenly depressed prices once the GOI's pharmaceutical spending cap is reached, drug companies will not see a sudden drop in revenues they would need to report and explain to their headquarters. Further, he held that (again) since prices do not drop suddenly, the reimbursement scheme does not encourage a parallel market in pharmaceutical purchasing by other EU countries once the GOI's spending cap is reached.

(SBU) 3. When informed about USG concern regarding the potential for generic drugs to be approved while patents for a branded drug are still in effect, Bianchi immediately responded that he was aware of the problem and was working to address it. He stated that the Italian Patent and Trademark Office (which reports to Bianchi) was working with AIFA (the Italian pharmaceutical regulatory agency) to find a solution that ensured that the approval process for generic drugs includes a comprehensive review of current drug patents, thus avoiding the possibility that a generic drug could be approved while a brand patent is still in effect. He expected the problem to be resolved soon, possibly "by year's end."

(SBU) 4. Bianchi expressed a willingness to discuss the pricing question and other issues with pharma industry

representatives in the future. He emphasized that the pharmaceutical industry is very important to the Italian economy. One of GOI's goals is to increase investment in innovation and R&D in Italy, and they see the pharma industry as a strong example of an innovative industry.

(U) 5. Bianchi relayed a new GOI plan to provide tax incentives for investment in R&D, particularly in private-public sector research partnerships. Both domestic and foreign companies can claim a 10 percent tax credit for 2007 spending (applicable in 2008) for direct investment in internal research, plus an additional 15 percent credit for R&D conducted with public universities or public sector agencies (external research), up to a total value of Euro 1.5 million per company. In 2008 the external research credit will increase to 40 percent (internal will remain at 10 percent), with the maximum deduction increased to Euro 5 million per company. The GOI estimates these credits will cost approximately Euro 600 million. Bianchi said the EU has recently approved this proposal.

(SBU) 6. COMMENT: Bianchi seems to be among the most forward-looking officials of the current GOI. The tax incentives, while mainly directed at small- to medium-sized Italian enterprises, illustrate his Ministry's intention to foster economic growth through innovative, research-oriented sectors, instead of just heavy, labor-intensive industry (e.g., factories with physical products). His willingness to engage with the pharma industry bodes well for pharmaceutical development here.

(SBU) 7. The Ministry of Economic Development's recent involvement in this issue provides a welcome counterbalance to the Ministries of Health and Finance, which are concerned

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almost exclusively with cost containment. END COMMENT.  
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